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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,217	04/09/2004	Antoine Kaldany	2013.2002-001	1319

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EXAMINER

KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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06/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,217

Applicant(s)

KALDANY, ANTOINE

Examiner

Sharon E. Kennedy

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/27/2004.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

Claim 23 is objected to because of the following informalities: It contains a typographical error in line 1 regarding claim dependency. It should be dependent upon claim "21", not claim "2". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 7-17, 20-26 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Yang, US 6,613,084. Note figure 1, cover 104 comprising drug chamber 106, layers 110, 108, and micro tubing 133 which may be connected to syringe 136. See examples 2 and 3 in columns 12 and 13, describing heparin released to the internal passageway. The claimed "tubular inner graft member positioned within the passage of the vascular graft device" (claim 12) is anticipated by the Yang inner stent. Time release drugs are disclosed in column 5, lines 42-44. Regarding claims 11, 23, the claims require that the drug is "at least near" the first and second ends of the graft

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device. In view that Yang drug chamber 106 extends throughout the length of the vascular implant, the claim limitation is met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 6 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang, '084 as applied to claims 1 and 16, and further in view of Herweck et al., US 5,411,550. Yang discloses the claimed invention including loading chamber 106 with drugs, which are defined as "any compound which has a desired pharmacologic effect." See column 5, lines 16-17. Yang does not explicitly mention using cells in drug chamber 106. Herweck discloses an similar device, including a semipermeable wall 14, outer impermeable wall 16. Herweck exemplifies that is it known to incorporate drug producing cells (column 3, lines 24-35) into the drug chambers of intravascular lumens,

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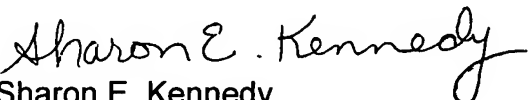
which would inherently function as an artificial organ. Accordingly, it would be obvious to one of ordinary skill in the art to use cells in the Yang device, in view that any drug can be included in Yang, as shown by Herweck, so that the usefulness of the Yang device can be extended into different drug therapy options.

Claims 4 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang, '084 as applied to claims 1 and 16, and further in view of Sullivan et al., US 6,187,038. Yang discloses all of the claimed embodiments including a sustained release polymer for drug delivery but fails to mention microspheres. Sullivan exemplifies that the use of microspheres in vascular grafts is well known to improve drug delivery. It would be obvious to one of ordinary skill in the art to employ microspheres in the Yang device as shown by Sullivan so that the Yang device could provide enhanced drug delivery.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.


Sharon E. Kennedy
Primary Examiner
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